

## REMARKS

Claims 1-5, 7-11 and 13-17 are pending in the application.

Claims 1, 7 and 13 are amended above to more clearly set forth what the Applicants regard as their invention. No new matter is added to the application by way of these amendments.

### I. THE SECTION 112, SECOND PARAGRAPH REJECTION

Claims 1-5, 7-11, and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 1, 7 and 13 have been amended so that in paragraph a) of each claim, potential tubules are indicated by pixel values at boundaries indicating epithelial layers. In paragraph b), second objects in the first image are indicated by pixel values not indicating epithelial layers but instead fat and holes within tubules. In paragraph c), second objects which are holes within tubules are indicated by their being within first objects. In paragraph d)ii), first objects are counted as being tubules if they have second objects within them. This is based *inter alia* on the specification at page 7 lines 19-22. Applicants trust these amendments overcome the 35 U.S.C. 112, second paragraph rejections of independent claims 1, 7 and 13 and their respective dependent claims 2-5, 8-11 and 14-17.

### II. THE SECTION 101 REJECTION

Claims 1-5 and 13-17 stand rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter.

Claim 1 has been amended so that the method is carried out using computer apparatus. Claim 13 has been amended to exclude non-physical carrier media. Moreover, the term "carrier medium" in the claims does not read on embodiments that are not physical computer program media. Applicants trust these amendments overcome the 35 U.S.C. 101 objection to claims 1 and 13 and their respective dependent claims 2-5 and 14-17.

### III. TRAVERSE OF THE ANTICIPATION REJECTION

Claims 1, 3-5, 7, 9-11, 13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al.. "A parallel approach to tubule grading in breast cancer lesions and its VLSI Implementation", Computer-based Medical Systems, 1991. Proceedings Of The Fourth Annual IEEE Symposium Baltimore, MD, USA 12-14 May 1991, Los Alamitos, CA, USA, IEEE Comput. Soc, US (12-05-1991), 322-329, XP-10024202 (submitted on IDS filed 7/25/2005, hereinafter "Cheng").

**A. The Cheng Prior Art**

Cheng section II discloses the following process:

- a) median filtering to eliminate noise and enhance preselected features;
- b) image thresholding to select higher intensity "bright cores";
- c) iteration of image extension and Laplacian operation to distinguish tubules with circular dark boundaries from rough texture lacking such boundaries. The circular dark boundaries have radii between two prearranged values  $R_{min}$  and  $R_{max}$ ; and
- d) counting total amount of tubule area.

**B. The Claimed Invention**

The application includes independent claims 1, 7 and 13. Each of the independent claims include similar steps or features so the Applicant's traverse of the rejection of claims for lacking novelty of Cheng will focus on independent claim 1 but will apply equally to independent claims 7 and 13.

Applicants' invention as claimed in claim 1(a) to 1(c) is described with reference to images illustrated in Figures 3-6. Figures 3-6 show respectively the greyscale first image 50 of a tissue specimen, second image 60 showing tubule-sized objects, a third image 70 showing holes cross-hatched and combining data from the second and third images to derive selected second objects 81.

**C. Claim Features Not Disclosed By Cheng**

"For a prior art reference to anticipate in terms of 35 U.S.C. Section 102, every element of the claimed invention must be identically shown in a single reference." Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 677, 7 U.S.P.Q.2d 1315, 1317 (Fed. Cir. 1988; emphasis added). The disclosed elements must be arranged as in the claim under review. See Lindemann Machinefabrik v. American Hoist & Derrick Co., 730 F.2d 1452, 1458, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984). If any claim, element, or step is absent from the reference that is being relied

upon, there is no anticipation. Kloster Speedsteel AB v. Crucible, Inc., 793 F.2d 1565, 230 U.S.P.Q. 81 (Fed. Cir. 1986; emphasis added). The following analysis of the present rejections is respectfully offered with guidance from the foregoing controlling case law decisions. All pending claims are novel at least because Cheng does not disclose the steps of Applicants' claim 1(a) to 1(c).

Applicants' claim 1(a), as now amended, relates to using the first image a first time to obtain appropriately sized objects with pixel values at boundaries indicating epithelial layers, and claim 1(b) to using that same image a second time but differently to find second objects having pixel values not indicating epithelial layers but instead fat and holes within tubules. Cheng does not disclose using the same first image twice for different purposes.

Applicants' claim 1(c) relates to combining data from the second and third images to identify as holes within tubules those selected second objects which are within first objects: there is no disclosure of this in Cheng. Cheng simply discloses successive stages in processing an image: each image is used once and then discarded (treating the iterative process of image extension and Laplacian operation as one "use" as it is merely detection of a single feature, a boundary). Cheng does not disclose combining data from two different images derived by processing a first image in two different ways to identify selected second objects within first objects, which is what claim 1(c) specifies.

As noted above, similar remarks regarding claim novelty apply to independent claims 7 and 13. Claims 1, 7 and 13 as now amended are therefore novel over Cheng for the purposes of 35 U.S.C. 102(b) as are their respective dependent claims 3-5, 9-11 and 15-17.

The differences between the claimed invention and the Cheng methods provide several important technical advantages. First off, the Cheng method is limited to circular tubule holes with radii in a predetermined range. (See Cheng page 322 last paragraph, third line "circular shapes", and page 324 lines 1 and 2, radii " $R_{min}$ " and " $R_{max}$ "). Here Cheng is quite wrong technically because, as discussed in Applicants' specification at page 7, lines 13-16, a "tubule is an image of a section through a mammary duct produced in the slide production process: it can appear round, oval, cylindrical or irregular depending on the angle of the section to the duct axis and the shape of the duct after sectioning". It must be remembered that tissue specimens are cut from tissue and tubule shape is dictated by the cutting process and its direction relative to a tubule axis. Cheng does not deal with or even recognise this.

It would also appear that Cheng is not workable with normal histopathology tubule specimens which have variable and possibly irregular tubule shapes. This is because Cheng relies on selecting successive circles of pixels ("at a most outer layer" page 324 third line from bottom) increasing in size in an image and obtaining a large Laplacian value when a circle lies on a boundary. (See Cheng, page 324 last two sentences). Clearly, a pixel circle cannot match an oval, cylindrical or irregular tubule. At best it can only match a part of such a tubule's circumference having the appropriate radius. Moreover, differently radiused pixel circles will match different parts of that circumference: consequently, instead of getting a sharp change from high to low in the resulting Laplacian to locate a tubule boundary, one will get a series of intermediate Laplacian values spread out over a variety of pixel circles and it will not be clear that a tubule has been located.

Furthermore, Cheng cannot compensate a tubule count for tubules having more than one hole - unlike Applicants' invention. Cheng discloses using pixel circles centered on respective holes and extending the circles outwardly to find a boundary indicated by a large change in Laplacian. This results in each hole being treated as belonging to a different tubule. As described with reference to Figure 9 in Applicants' specification at page 12 line 20 onwards, a tubule may have more than one hole and Applicants' invention can be adapted to correct the tubule count for this whereas Cheng cannot.

## **CONCLUSION**

The pending application claims are believed to be ready for patenting for the reasons recited above. Favorable reconsideration and allowance of all pending application claims is courteously solicited.

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